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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/068,812	02/04/2002	Richard J. Greff	034298-122	8436

7590 06/23/2006

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 06/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/068,812	GREFF, RICHARD J.	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 April 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicant's amendment filed 04/07/2006.

Claims 1-19 previously presented, and claims 20 and 21 have been added.

Claims 1-21 are pending and included in the prosecution.

The following rejection has been overcome by virtue of applicant's amendment:

The rejection of claims 5-8, 10, 12-14, and 17 under 35 U.S.C. 112 second paragraph, as being indefinite.

The following rejection has been discussed in the previous office action, and are maintained for reasons of record:

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-9, 11-13, 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 02-182259 (259).

JP '259 disclosed composition comprising crosslinked gelatin, and solution comprising surfactant impregnated into the crosslinked gelatin (see the provided abstract). The composition comprises 1-50 % of gelatin in aqueous solution and from 0.1 % to 30 % of the aqueous solution is the surfactant (page 5, last paragraph; page 6, first full paragraph). The reference disclosed in the process of making the composition, the gelatin solution is prepared, then, the surfactant is added followed by foaming and drying, i.e. evaporation of the solvent (page 6, second full paragraph; page 10, operational example 1). The addition of the surfactant to the gelatin solution reads on mixing of claims 3 and 6, impregnation of claims 2 and 7, and coating on the surface of the gelatin solution of claim 4, 8 and 12 because claim 12 recites the coating is achieved by applying solution of the wetting agent on the surface of the gelatin solution. The composition easily dissolves in blood or body fluids, i.e. bioabsorbable (page 7, third line). The surfactants disclosed by the reference include sodium lauric sulfuric acid, polyethylene glycol alkyl ether and sorbitan fatty acid ester (page 7, second full paragraph). Decreasing the hydration time of the cross-linked gelatin that claimed in claims 5 and 19 is inherent in the material of the reference that comprises cross-linked gelatin and the same wetting agent. Furthermore, on page 5, lines 25-27 of the present disclosure, applicants disclosed that the hydration time is the time needed to prepare the gelatin for use, and the reference disclosed on page 11, third full paragraph that hemostatic composition showed slight swelling and arrested bleeding in 60 seconds, i.e. the composition was ready for use.

Response to Arguments

3. Applicant's arguments filed 04/07/2006 have been fully considered but they are not persuasive.

The main gist of applicant's argument against the anticipatory rejection under 35 U.S.C. 102 (b) over Yasushi (JP '259) is that the reference fails to disclose or suggest a cross-linked gelatin composition including a sufficient amount of a wetting agent solution incorporated into a cross-linked gelatin, or method that includes incorporating a biocompatible wetting agent solution with said cross-linked gelatin. Yasushi disclosed that the surfactant is not incorporated into a cross-linked gelatin, as specified in the claims, but instead into a simple gel solution that is cross-linked afterwards. Applicant argues that the present independent claims 1, 5, 18 and 19 specify a biocompatible, hemostatic, cross-linked gelatin composition including a sufficient amount of a wetting agent solution incorporated into a cross-linked gelatin. Yasushi does not anticipate the present claims and no *prima facie* case of obviousness has been established over Yasushi.

In response to this argument, the examiner position is that independent claims 1, 5, 18 and 19, and claims dependent therefrom that included in the rejection, do not require cross linking before the addition of the wetting agent. Independent claims 1 and 18 are directed to composition comprising cross linked gelatin and wetting agent, and these requirement are met by the Yasushi's reference. Independent claims 5 and 19 requires a step to be performed prior to hydrating the gelatin, and this step is the

incorporation of the wetting agent with the gelatin, and does not require incorporation of the wetting agent into the previously cross linked gelatin. Decreasing the hydration time of the cross-linked gelatin that claimed in claims 5 and 19 is inherent in the material of the reference that comprises cross-linked gelatin and the same wetting agent because the properties and compounds are not separable. Furthermore, on page 5, lines 25-27 of the present disclosure, applicants disclosed that the hydration time is the time needed to prepare the gelatin for use, and the reference disclosed on page 11, third full paragraph that hemostatic composition showed slight swelling and arrested bleeding in 60 seconds, i.e. the composition was ready for use.

The product of the prior art comprises cross-linked gelatin and wetting agent that has hemostatic effect and has decreased hydration time. Therefore, Yasushi anticipates claims 1-9, 11-13, 17-19.

The following new grounds of rejection are necessitated by applicant' amendment, wherein claim 10 is not included in this rejection and the new claims 20 and 21 are included:

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 14-16, 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP '259 in view of US 6,603,061 ('061).

The teachings of JP '259 are discussed under 102 rejection above. However, JP '259 does not teach that the composition comprising thrombus enhancing agent (claim 20) or antimicrobial agent (claim 21), the amount of the wetting agent in the gelatin composition after evaporation of the solvent (claim 14), the composition is sterilized and packaged (claim 15), and the kit of syringe and pledget (claim 16).

It is expected to one having ordinary skill in the art to adjust the drying and evaporation of the solvent in order to obtain the desired concentration of the wetting agent in the composition, and the claimed concentration of the wetting agent in claim 14 does not impart patentability to the claims, absent evident to the contrary. Further, inclusion of active agents beneficial to the wound in a wound dressing composition, as well as sterilizing and packaging of wound dressings are well known in the art.

US '061 teaches a biocompatible hemostatic composition comprising non-hydrated cross-linked gelatin, plasticizer and hydrating agent (col.3, lines 4-6, 43, 67; col.4, lines 11-12, 41-42; col.5, line 40; col.8). The composition further comprises active agent such as antibiotics and hemostatic agents including thrombin and clotting factors (col.11, lines 16-35). The composition can be in the form of sterile packaged kit comprising the composition and a syringe and can be extruded from the syringe into intervertebral spaces, holes and pockets (col.3, lines 33-34; col.5, lines 6-10, 25-35; col.8, lines 32-36).

Therefore, it would have been obvious to one having ordinary skill in the art at he time of the invention to provide the hemostatic composition disclosed by JP '259 and add antimicrobial and/or clotting factors that are beneficial for hemostasis and deliver it by a syringe as disclosed by US '061, motivated by the teaching of US '061 that delivering the composition from a syringe allows the extrusion into intervertebral spaces, holes and pockets, with reasonable expectation of having sterile hemostatic composition delivered from syringe into sites that are difficult to access and require such a hemostatic treatment.

Response to Arguments

6. Applicant's arguments filed 04/07/2006 have been fully considered but they are not persuasive.

Applicants traverse the obviousness rejection of claims 10 and 14-16 under 35 U.S.C. 103(a) over Yasushi in view of U.S. Patent No. 6,063,061 for Wallace ('061) by arguing that independent claim 16, as well as claim 17 dependent thereon, recites a kit of parts including, a pledget consisting of a wetting agent incorporated into a cross-linked gelatin, similar to independent claims 1, 5, 1 8, and 19 discussed supra. Neither Yasushi nor Wallace disclose or suggest this element, and therefore no combination of Wallace and Yasushi teaches or suggests all of the elements of claim 16.

In response to this argument, the examiner position is that independent claim 16 and claim 17 that depends therefrom, do not require cross linking before the addition of

the wetting agent. Independent claim 16 is directed to product comprising pledget of cross linked gelatin and wetting agent, and a syringe, and Yasushi disclosed the composition of the pledget. Wallace is relied upon for teaching the syringe to deliver the hemostatic composition. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it would have been obvious to one having ordinary skill in the art at he time of the invention to provide the hemostatic composition disclosed by JP '259 and add antimicrobial and/or clotting factors that are beneficial for hemostasis and deliver it by a syringe as disclosed by US '061, motivated by the teaching of US '061 that delivering the composition from a syringe allows the extrusion into intervertebral spaces, holes and pockets, with reasonable expectation of having sterile hemostatic composition delivered from syringe into sites that are difficult to access and need hemostatic treatment.

It is well established that the claims are given the broadest interpretation during examination. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are

evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been *prima facie* obvious within the meaning of 35 U.S.C. 103 (a) over Yasushi in view of Wallace.

7. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over JP '259 in view of EP 5568 334 ('334).

The teachings of JP '259 are discussed under 35 U.S.C.102 rejection above. However, JP '259 does not teach that the composition comprising growth factor as instantly claimed in amended claim 10.

EP '334 teaches collagen containing sponge comprising cross linked gelatin and active agent, preferably growth factors which enhance wound healing and nerve regeneration (abstract; col.5, lines 22-30).

Therefore, it would have been obvious to one having ordinary skill in the art at he time of the invention to provide hemostatic composition comprising cross linked gelatin and wetting agent as disclosed by JP '259, and add growth factors to the composition as disclosed by EP '334, motivated by the teaching of US '334 that growth factors are preferred active ingredient to be added to hemostatic gelatin wound treating composition because growth factors enhance wound healing and nerve regeneration, with reasonable expectation of having composition comprising cross linked gelatin,

wetting agent and growth factors wherein the composition enhances wound healing and nerve regeneration.

Claim Objections

8. Claims 5 and 19 are objected to because of the following informalities: the claims miss the word "gelatin" in the second line of each claim after the phrase "cross linked" in the beginning of line 2, and before the word "composition". Appropriate correction is required.

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5,595,735 disclosed hemostatic composition comprising polyethylene glycol adsorbed on gelatin sponge; col.2, lines 35-66. US 4,920,158 disclosed hemostatic composition comprising crosslinked gelatin (GELFOAM) and glycerin, example 1.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615

Isis Ghali